

Response to Office Action of: 08/11/2005
Response Dated: 10/11/2005
Title: Gel And Cushioning Devices

App. No.: 09/121,300
Inventor: Bruce G. Kania et al.
Examiner: David H. Willse

REMARKS/ARGUMENTS

Attorney Docket Number

Applicant would like to inform the Examiner that it is represented by new counsel in the present matter. As such, Applicant respectfully requests that the Attorney Docket Number for the present case be changed from "3295-0024-0CONT" to "OHI 1717-096." Applicant also respectfully requests that the Examiner use this new docket number in all future correspondence relating to the present application. Applicant would also like to inform the Examiner that a change in Power of Attorney was submitted to the PTO several months ago with respect to the present application, but appears to not yet have been recorded.

In the Claims:

Rejection of Claims Under 35 U.S.C. § 112

The Examiner rejected claims 75-78, 80, 85, 88, 89, 92-94, 96, 99, 102, 103, 106, 107, 110, 111, 114, 115, 118-121 and 124-165 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not adequately described in the specification. More specifically, the Examiner asserts that the ability of the polymeric cushioning material to form an air-tight seal with an amputation stump is not supported by the original disclosure. Based on this assertion, the Examiner has issued a first office action final rejection. Applicant respectfully disagrees with the Examiner's conclusion that the foregoing limitation is not supported by the original disclosure. In an attempt to expedite allowance of the present application, however, Applicant has

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amended the claims to recite a "polymeric cushioning gel" as opposed to a "polymeric cushioning material."

As mentioned by Applicant in its previous reply, support for the ability of the polymeric material of the present invention to provide an air-tight seal with an amputation stump can be found throughout the specification of the present application, as well as throughout the specification of U.S. Patent No. 5,830,237 (the '237 patent), of which the present application is a continuation. For example, Applicant specifically pointed out that on page 3, lines 1-3 of the present application, as well as at column 1, lines 55-57 of the '237 patent, it is clearly stated that Applicant considers a "polymeric material" to be non-breathable. This statement was made when explaining why pistoning of an amputation stump within a prosthetic socket is not a problem when the amputee uses wool and cotton (breathable) socks, but is a problem when the amputee uses a polymeric sock. It is further recited that a sock of the present invention avoids the generation of obtrusive sounds caused by air pockets between an amputee's residual limb and the sleeve member (sock) or between the sleeve member (sock) and the prosthetic socket. (See col. 7, ll. 49-53 of the '237 patent). As was pointed out earlier in the disclosure, these air pockets are a common result of wearing a breathable sock. Thus, Applicant clearly distinguished polymeric (non-breathable) socks from breathable (e.g., wool and cotton) socks in the original disclosure.

Even without this support, however, Applicant asserts that one skilled in the art of polymers would understand from the totality of the disclosure that the polymeric cushioning gel recited in the present application is capable of forming an air-tight seal with an amputation stump. The polymeric material is described as being a polymeric

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"gel" - indicating that the material is semi-rigid. (See, e.g., col. 4, ll. 1-2 of the '237 patent). It is also stated that the gel (polymeric material) preferably has a durometer of between 1-20 Shore A, or some other durometer that approximates that of human skin. (See col. 5, ll. 7-9; and col. 10, ll. 29-36 of the '237 patent). The original disclosure also recites that the polymeric material is preferably a S-I-B, S-E-P, S-B-S or S-E-B-S block copolymer. (See, e.g., col. 5, ll. 12-14 and col. 10, ll. 18-26 of the '237 patent). Specific examples of such block copolymers are said to include C-Flex 1970-W5 and C-Flex 1960-W5 polymers from Consolidated Polymer Technologies, and Kraton G1654 from Shell Chemical Co. (See e.g., col. 5, ll. 14-19 of the '237 patent).

In addition to the foregoing characteristics, formulations and commercially available examples of preferred polymeric materials, it is also discussed at length that mineral oil is preferably mixed into the polymeric gel. (See col. 4, line 1 to col. 5, line 7; and col. 5 ll. 19-31 of the '237 patent). One skilled in the art would understand that mineral oil would further contribute to the softness and pliability of the polymeric material, and enhance its ability to conform to an amputation stump (i.e., form an air-tight seal therewith). The polymeric material may also be some blend of Kraton or other similar rubbers and oils that provides for the desired durometer range. (See col. 10, ll. 37-43 of the '237 patent).

It is realized that in order for the polymeric material to provide an air-tight seal to an amputation stump, the material used must not only be capable of substantially preventing air permeation, but must also be able to conform closely to the amputation stump. The polymeric material of the present invention has such characteristics. As stated in the original disclosure, "[t]he blends ... are capable of providing a form fit to the

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residuum due to their inherent elasticity ... [and] tend to have a sticky feeling which, when present in the polymeric cushioning material, tends to enhance the form fitability of the sleeve [sock] essentially by mating it against the skin." (Col 10, ll. 43-50 of the '237 patent).

Consequently, it can be seen that substantial disclosure relating to the non-breathable characteristic of a polymeric gel of the present invention was provided in the as-filed application. Further, in light of the stated gel characteristics, the specific block copolymer forms, and the commercially available material examples present in the original disclosure, one skilled in the art would clearly understand that the polymeric cushioning gel is capable of forming an air-tight seal with an amputation stump when a cushion liner of the present invention is worn.

In addition to the foregoing, Applicant submits that the Examiner has failed to address specific examples of support presented in its previous reply, and also appears to misunderstand certain features of the present invention. With respect to the previous reply of Applicant, the Examiner wholly failed to address the areas of the specification that were cited by Applicant to support its contention that the original disclosure contemplated a non-breathable gel material capable of forming an air-tight seal with an amputation stump. Rather, the Examiner simply states that the specific language "capable of forming an air-tight seal with said amputation stump when said liner is worn" is not found anywhere in the original disclosure. While Applicant readily admits that this particular sentence does not appear in the original disclosure, Applicant submits, based upon the above remarks, that such can be clearly understood by one skilled in the art from a reading of the original disclosure.

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The Examiner also infers that because the cushion liner may be designed in a recessed Achilles fashion (i.e., the cushioning material may be thinned or absent in an area corresponding to the rear of the amputees knee) or the cushioning material may be tapered or feathered as the open end is approached, it is not possible for the polymeric material to form an air-tight seal with an amputation stump. It appears that the Examiner may have misunderstood what is described by these constructions. In the former construction, only a small section of the polymeric material is removed from the liner, or thinned. (See Fig. 7a). This section corresponds in position to the crease behind an amputees knee and helps reduce binding when the liner is worn. However, this recessed Achilles configuration does not prevent the polymeric material from forming an air-tight seal with the amputation stump, because the remainder of the polymeric material between the recessed Achilles area and the distal end of the liner is still present. Similarly, the latter embodiment does not prevent the polymeric material from forming an air-tight seal with the amputation stump because the remainder of the polymeric material between the tapered or feathered area and the distal end of the liner is still present, and because the tapered or feathered area will likely still be in contact with the skin due to its flexible nature. (See Fig. 6),

The Examiner also asserts that the presence of an optional docking means teaches against the forming of an air-tight seal. First, many of the rejected claims do not recite a docking means, so the Examiner appears to be impermissibly reading a limitation of one exemplary embodiment described in the written description into the claims. Second, due to the use of appropriate construction techniques, it is entirely possible to form an air-tight seal between a liner interior and an amputation stump when

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a docking means is present. (See col. 6, ll. 54-57, col. 7, ll. 26-30, and Fig. 9 of the '237 patent for an explanation of how the docking means does not need to penetrate the liner interior). Thus, pistoning of the amputation stump within the liner would be eliminated, even if a suction socket were not used. Additionally, it is also possible to form a suction socket when a docking means is present. There are a number of devices adapted for inclusion in or attachment to a prosthetic socket, which devices are capable of receiving a locking pin extending from a prosthetic liner while still maintaining a seal with the socket. Such devices may use o-rings or other sealing elements to prevent vacuum loss. These devices would be well known to one skilled in the art.

The Examiner additionally asserts that the use of an inner piece of fabric or a foamed gel requires the conclusion that the polymeric material cannot form an air-tight seal with the amputation stump. Again, however, the Examiner is importing limitations from exemplary embodiments described in the written specification into the claims. The rejected claims do not recite a non-foamed polymeric material, nor do they recite the use of an inner piece of fabric material. These are simply alternate embodiments of the present invention that Applicant has not chosen to claim. The fact that these alternate embodiments are possible does not mean that the embodiments Applicant has chosen to claim are unsupported by the original disclosure. Further, Applicant believes that it is possible to create a foamed polymeric material that could still provide an air-tight seal.

As a result of the above claim amendments and foregoing remarks, Applicant respectfully submits that there is support for the present claim language and that present application is, therefore, now in condition for allowance. However, if the Examiner again rejects the present application, it is requested that the Examiner at least

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withdraw the final status of his rejection in light of the fact that he did not specifically address the arguments put forth by Applicant in its last reply.

CONCLUSION

Applicant has amended the claims to more specifically describe the nature of the polymeric material recited therein. Applicant has also provided ample references to the original disclosure that support the ability of the polymeric cushioning gel to form an air-tight seal with an amputation stump.

Therefore, Applicant respectfully submits that the present application is now in condition for allowance, and entry of the present amendment and allowance of the application as amended is earnestly requested. If, however, the Examiner maintains his rejection, entry of the present amendment is respectfully requested as reducing the number of issues and placing this application in better condition for appeal.

Telephone inquiry to the undersigned in order to clarify or otherwise expedite prosecution of the present application is respectfully encouraged.

Respectfully submitted,

Date: 10/11/05

By: _____



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